

**AUG - 1 2003**

Vascular Architects - 510(k) Premarket Notification  
**Vascular Architects aSpire®** Covered Stent  
and **718™** Delivery System

1/2

## **ATTACHMENT A**

### **510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K031641**

### **APPLICANT INFORMATION**

**Date Prepared:** 5 June 2003

**Name:** Vascular Architects, Inc.  
**Address:** 1830 Bering Drive  
San Jose, CA 95112

**Contact Person:** Phyllis Elson  
**Phone Number:** (408) 392-7437  
**Fax Number:** (408) 453-7970

### **DEVICE INFORMATION**

**Trade Name:** **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System

**Common Name:** Tracheal Stent

**Classification Name:** Tracheal Prosthesis

**Performance Standards:** Performance standards have not been established by the FDA under section 514 of the Federal Food Drug and Cosmetic Act.

**Device Description:** The **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System consists of two principal components: a covered stent and a disposable delivery system.

**Equivalent (Predicate) Devices:**

K003173: **Vascular Architects aSpire®** Covered Stent and Delivery Catheter  
K012544: **Vascular Architects aSpire®** Covered Stent and **CONTROLLED EXPANSION®** Delivery System  
K030567 **Vascular Architects aSpire®** Covered Stent and **CONTROLLED EXPANSION®** Delivery System - 15cm stent length

**Intended Use:**

The **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.

**Comparison To Predicate Device:**

**Vascular Architects aSpire®** Covered Stent and **718™** Delivery System has the same intended use and technological characteristics as the predicate device.

The materials used to manufacture the **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System are similar to the materials used to manufacture the predicate device.

The available lengths and diameters of the **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System are similar to the lengths and diameters available for the predicate device.

**Non-clinical Test Results:**

Bench testing was conducted comparing the **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System to the predicate device. Results of bench testing performed demonstrate that the mechanical integrity and device performance of the subject device is substantially equivalent to that of the predicate device.

**Conclusion:**

The **Vascular Architects aSpire®** Covered Stent and **718™** Delivery System is substantially equivalent to the legally marketed **Vascular Architects aSpire®** Covered Stent and **CONTROLLED EXPANSION®** Delivery System.



AUG - 1 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Phyllis Elson  
Sr. Director, Regulatory Affairs  
Vascular Architects, Inc.  
1830 Bering Drive  
San Jose, California 95112

Re: K031641

Trade/Device Name: Vascular Architects aSpire<sup>®</sup> Covered Stent and  
718<sup>™</sup> Delivery System

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal prosthesis

Regulatory Class: II

Product Code: JCT

Dated: May 27, 2003

Received: May 27, 2003

Dear Ms. Elson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Phyllis Elson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K031641

Device Name: **Vascular Architects aSpire® Covered Stent and 718™ Delivery System**

**Indications for Use:** The **Vascular Architects aSpire® Covered Stent and 718™ Delivery System** is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-the-Counter Use \_\_\_\_\_

(Optimal Format 1-2-96)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K031641